MAR 1 4 2014

K133608

510(k) Summary

[As Required By 21 CFR 807.92]

General Information [21 CFR 807.92 (a)(1)]

Submitter Name/Address: Bicon, LLC
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Date: December 18, 2013

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Device Name [21 CFR Part 807.92 (a)(2)]
The device falls within the scope of the Guidance Document "Dental Composite Resin Devices – Premarket Notification [510(k)] Submissions" issued on October 26, 2005 fitting in the following:

Trade Name	Common Name	Device	Classification	Class	Product Code
TRINIA	Dental CAD/CAM Material	Tooth Shade Resin Material	21 CFR 872.3690	II	EBF

Predicate Devices [21 CFR 807.92 (a)(3)]

Device Name	Manufacturer	510(k) #	Date Cleared
Fiber Disk and Block Permanent	Bioloren S.r.l.	K121735	February 21, 2013

Description of the device [21 CFR 807.92 (a)(4)]
TRINIA is a fiber machining disk block. It is made of layers of glass fibers kept together by epoxy resin. TRINIA products are designed for the manufacturing of non-metallic dental appliances. The dental appliance is machined either by a CAD/CAM machine or by using the copying technique. TRINIA already possesses the mechanical characteristics needed for producing these dental appliances; no curing is necessary at the dental lab to make the product function properly.

Intended use [21 CFR 807.92 (a)(5)]
Fiber Disks and Blocks (TRINIA) are intended to be used for making copings, substructures, removable dentures, or frameworks for permanent and transitional anterior or posterior crowns, bridgework, and substructures that can be for either cemented or uncemented restorations (e.g. telescopic restorations).

(The Summary of technological characteristics is formatted in landscape orientation for ease of reading.)

Summary of technological characteristics [21 CFR 807.92 (a)(6), (b)]

The intended use and critical specifications (flexural strength, physical form, and solubility) of TRINIA are substantially equivalent to the predicate devices Bioloren Fiber Disk and Block Permanent. The following table details the comparison:

Descriptive Info	**Bicon TRINIA (New Device)**		**Bioloren Fiber Disk and Block Permanent (Predicate)**	
Intended Use – including the indications for use	Fiber Disks and Blocks (TRINIA) are milling blanks composed of a multi-directional interlacing of fiberglass and resin in several layers. They are intended to be used solely by dental technicians and dentists for making copings, substructures, removable dentures, or frameworks for permanent and transitional anterior or posterior crowns, bridgework, and substructures that can be for either cemented or uncemented restorations (e.g. telescopic restorations).		Fiber Disks and Blocks are milling blanks composed of a multi-directional interlacing of fiberglass and resin in several layers. They are intended to be used solely by dental technicians and dentists for making only copings, substructures, or frameworks for permanent and transitional anterior or posterior crowns, bridgework, and substructures that can be for either cemented or uncemented restorations e.g., telescopic restorations.	
Composition of Materials – the chemical composition of the device	Glass fiber Modified epoxy resin		Glass fiber Modified epoxy resin	
Physical Properties – e.g., compressive strength, flexural strength, particle size range, depth of cure	Flexural strength	393 MPa (N/mm^2)	*Flexural strength	302 MPa (N/mm^2)
	Flexural strain at max stress	2.7%	*Flexural strain at max stress	5.5%
	Flexural modulus of elasticity	18.8 GPa	*Flexural modulus of elasticity	12.6 Gpa
	Tensile strength	169 MPa (N/mm^2)	Tensile strength	--
	Tensile modulus of elasticity	18.8 Gpa	Tensile modulus of elasticity	--
	Compression strength Parallel to laminate	347 MPa (N/mm^2)	Compression strength Parallel to laminate	--
	Compression strength Perpendicular to laminate	339 MPa (N/mm^2)	Compression strength Perpendicular to laminate	--
	Charpy impact	26 KJ/m^2	Charpy impact	--
	Rockwell hardness (R scale)	125	Rockwell hardness (R scale)	--
	Barcol hardness	63	Barcol hardness	--
	Shore hardness	92.5	Shore hardness	--
	Density / Specific gravity	1.68 g/cm^3	Density / Specific gravity	--
	Water absorption	0.03%	Water absorption	--
	Short beam shear	49 N/mm^2	Short beam shear	--
FDA-Recognized Standards	ISO 10993-3	Non-mutagenic	ISO 10993-3	--
	ISO 10993-5	Does not induce cytotoxicity	ISO 10993-5	--
	ISO 10993-10	Non-irritant	ISO 10993-10	--
	ISO 10993-11	No adverse physical symptoms after injection	ISO 10993-11	--

* Results obtained from direct comparison testing.

Identification of the risk analysis method
Bicon has conducted a preliminary hazard analysis which identified risks, including risk of mechanical failure, toxicity and adverse tissue reaction, improper use, and incompatibility with other dental devices. The Failure Modes Effect Analysis (FMEA) showed that all risks, when reduced as far as possible, were acceptable. There were no risks that were so severe as to cause severe damage or lead to the death of a patient. The mechanical properties of the device are comparable to predicate devices. The biocompatibility testing of the composite resin device showed that TRINIA is biocompatible. The labeling of the device was designed to alert the user of any residual risks or warnings.

Discussion of the device characteristics
To reduce the risk of mechanical failure, TRINIA was designed to have a high compressive and flexural strength to withstand the chewing forces. In order to achieve this, the materials and the weave of the fabric were essential to the design; a weave that was too tight could result in the device not able to be cut with standard milling tools, while a weave that was too loose might result in a weaker compressive and flexural strength. In addition, the device was designed to be insoluble to water which is of importance in the oral cavity. This characteristic prevents breakdown of the device as well as preventing the device from entering the patient's body in a manner not intended by the manufacturer. A third characteristic that reduces the risk of mechanical failure of TRINIA is that the operator of the device does not need to perform any additional steps to make TRINIA function at the mechanical specifications. There are no curing steps needed; only milling of the dental appliance is required. This prevents improper fabrication due to varying curing or working times. The possibility of varying depth of cure is also avoided.

To reduce the risk of toxicity and adverse tissue reaction, TRINIA was tested against biocompatibility standards as specified by ISO 7405:2008, Dentistry – Evaluation of biocompatibility of medical devices used in dentistry. TRINIA is made out of materials that are not deadly in the health hazard rating and cause no cytotoxic effects.

To reduce the risk of improper use, TRINIA was designed to have the fewest steps possible for the user. As stated earlier to reduce the risk of mechanical failure, there are no curing steps required. This reduces the possibility of the user performing the curing incorrectly, as there are no curing steps. The working time for TRINIA is therefore extended and the user does not need to rush to finish the dental appliance.

Description of the performance aspects (21 CFR 807.92 (b)(1)(2))
The testing of the performance aspects was performed to recognized standards, such as ASTM or ISO. The following table lists the test and the test method used to obtain the actual result shown.

Physical Properties

Test Name	Standard	Units	Result
Flexural strength	ISO 14125	MPa (N/mm^2)	393
Flexural modulus of elasticity	ISO 14125	Gpa	18.8
Tensile strength	ASTM D3039	MPa (N/mm^2)	169
Tensile modulus of elasticity	ASTM D3039	Gpa	18.8
Compression strength	ASTM D6641	MPa (N/mm^2)	347
Charpy impact	ISO 179	KJ/m^2	26

Test Name	Standard	Units	Result
Rockwell hardness (R scale)	ISO 2039-2	--	125
Barcol hardness	ASTM D2583	--	63
Shore hardness	ASTM D2240	--	92.5
Density / Specific gravity	ISO 1183	g/cm^3	1.68
Water absorption	ASTM D570	%	0.03
Short beam shear	ASTM D2344	N/mm^2	49

Biocompatibility

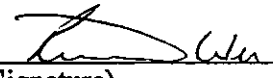
Test Name	Standard	Criteria	Result
Genotoxicity	ISO 10993-3	Non-mutagenic	Non-mutagenic
Cytotoxicity	ISO 10993-5	Non-cytotoxic	Non-cytotoxic
Irritation or Intracutaneous Reactivity	ISO 10993-10	Non-irritant	Non-irritant
Acute Systemic Toxicity	ISO 10993-11	Non-toxic	Non-toxic

* NS = Not Specified

Clinical testing is not required to demonstrate substantial equivalence as the indications for use is similar to legally marketed devices, the design is similar to designs previously cleared under a premarket notification, and the technology used in TRINIA is not a new technology.

Reliance on standards
Testing has been performed to the standards listed in the "Description of the performance aspects" section. A FDA Form 3654 has been completed for each of the standards listed in this 510(k). There were no deviations to the procedure of the standard for the tests performed.

Conclusion
TRINIA is substantially equivalent in safety and effectiveness to the predicate device based on the results of the physical property and biocompatibility testing. There are no substantive differences in the indications for use or technology, including features, materials, and principals of operations, from the predicate device.



(Signature)

Richard Wu
(Typed Name)

December 18, 2013
(Date)

K133608
(Premarket Notification [510(k)] Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 14, 2014

Bicon, LLC
Richard Wu
501 Arborway
Boston, MA 02130

Re: K133608
Trade/Device Name: TRINIA
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Codes: EBF, EBG, EBI
Dated: December 18, 2013
Received: December 20, 2013

Dear Mr. Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
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Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
Fiber Disks and Blocks (TRINIA)

Indications for Use *(Describe)*
Fiber Disks and Blocks (TRINIA) are milling blanks composed of a multi-directional interlacing of fiberglass and resin in several layers. They are intended to be used solely by dental technicians and dentists for making copings, substructures, removable dentures, or frameworks for permanent and transitional anterior or posterior crowns, bridgework, and substructures that can be for either cemented or uncemented restorations (e.g. telescopic restorations).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Mary S. Runner -S
2014.03.14 15:02:04 -04'00'

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